REMARKS

The present Response does not introduce any amendments to the claims pending in the Application.

The Examiner has rejected Claims 1-11, 17-24, 27-33, and 39-45 under 35 U.S.C. § 102(b) as being anticipated by European Patent Application EP 0 562 864 to Rosenthal et al. ("the Rosenthal et al. '864 Application"). Applicants respectfully traverse this rejection for the reasons discussed herein.

The biocompatible product covered by the independent claims of the present Application (i.e., Claims 1, 2, 25, and 40-45) includes a (1) biocompatible, biodegradable anionic or cationic carrier; (2) a pharmaceutically active agent which is ionically linked to the carrier, forming a carrier/active agent combination; and (3) an enclosing means for enclosing the carrier/active agent combination. The plain meaning of "enclose" is "to surround on all sides" (see first definition of "enclose" in Webster's II New College Dictionary. 2001. Houghton Mifflin Company). Thus, the enclosing means of the independent claims should be understood to surround the carrier/active agent combination on all sides. Further, independent Claims 1, 25, 40, 42, 43, and 45 of the present Application recite that the enclosing means has an outwardly directed surface having a predetermined permeation gradient for passage of a pharmaceutically active agent through the outwardly directed surface.

In contrast to the teaching of the present Application, the Rosenthal et al. '864 Application teaches a porous bioabsorbable implant which is "structurally inhomogeneous due to the presence of substructures in the sponge matrix" (emphasis

added) (see Col. 3, lines 15-18). The structure of the otherwise homogeneous sponge matrix is interrupted by the substructures (see Col. 5, lines 17-20). These interruptions create voids that provide paths along which cells may preferentially migrate into the implant. The substructures may include bioabsorbable films or film fragments (see Col. 5, lines 15-17). Example 3 of the Rosenthal et al. '864 Application illustrates the formation of a bioabsorbable implant, wherein the following steps are performed: (1) extruding a gel or slurry of collagen to form a film (Col. 5, lines 20-31); (2) forming a layer of a sponge gel or slurry on a tray (Col. 5, lines 43-46); (3) placing the collagen film formed in step 1 onto the sponge layer of step 2 (Col. 5, lines 46-48); and (4) forming a second layer of collagen sponge on top of the collagen film (Col. 5, lines 48-49). The collagen film thus forms a substructure between the two layers of sponge matrix. The Rosenthal et al. '864 Application also teaches that fragmented substructures may be premixed within a gel, paste, slurry or emulsion from which the sponge matrix is formed (Col. 5, lines 24-28). Applicants also note, with respect, that Examiner Fubara has acknowledged that the substructures taught by the Rosenthal et al. '864 Application are embedded within the sponge matrix (see numbered paragraph 3 on page 2 of the Office Action). The embedded substructures of the Rosenthal bioabsorbable implant cannot be said to surround the implant's sponge matrix. In fact, the Rosenthal et al. '864 Application does not include any teaching of a substructure that surrounds the sponge matrix of the bioabsorbable implant. Applicants respectfully request that, if the Examiner is aware of such a teaching in the Rosenthal et al. '864 Application, the Examiner assist Applicants by stating the specific column and line numbers at which such a teaching may be found. Further, the Rosenthal et al. '864

Application does not teach the use of any means for predetermining a permeation gradient for passage of a pharmaceutically active agent, or the presence of an enclosing means, or any substructure, which has an outwardly directed surface. Again, Applicants respectfully request that, if the Examiner is aware of such a teaching in the Rosenthal et al. '864 Application, the Examiner assist Applicants by stating the specific column and line numbers at which such a teaching may be found.

Applicants also respectfully note that the biocompatible product of the present Application could not be obvious over the bioabsorbable implant of the Rosenthal et al. '864 Application. For a claimed invention to be obvious over a reference, or a combination of references, the reference must suggest the combination of features present in the claimed invention. There is no such suggestion in the Rosenthal et al. '864 Application. The main purpose of the heteromorphic sponge taught by the Rosenthal et al. '864 Application is to facilitate migration of cells into the matrix of the sponge. The pores in the outer surface of the sponge, as well as the openings within the matrix that are formed by the embedded substructures, allow the cells to penetrate into the interior of the implant. A primary purpose of the biocompatible product of the present invention is to control the release of pharmaceutically active agents from the carrier/active agent matrix through the enclosing means. The enclosing means, with its predetermined permeation gradient, provides such control. The Rosenthal et al. '864 Application, although it teaches the phasic release of pharmaceutically active agents from the sponge matrix, neither teaches nor suggests that enclosing the sponge matrix will beneficially control the release of such active agents. It actually teaches away from such a concept by

teaching that the exterior surface of the implant is formed by the sponge matrix. Further, Applicants respectfully submit that it would be improper to modify the bioabsorbable implant of the Rosenthal et al. '864 Application by adding an enclosing means. Such a modification of the implant would defeat the purpose of the heteromorphic sponge, since the enclosing means would inhibit the movement of cells into the sponge matrix from its external environment, thus making the implant inoperable.

In the foregoing circumstances, Applicant's attorney respectfully submits that the claims of the present Application distinguish over the Rosenthal et al. '864 Application and requests that the Examiner withdraw the rejection made under 35 U.S.C. § 102(b). Moreover, Applicant's attorney respectfully submits that the claims depending from Claims 1 and 2 that were rejected under § 103(a) are also in condition for allowance, specifically, Claims 12-16 and 34-38, which were rejected over the Rosenthal et al. '864 Application, and Claims 25 and 26, which were rejected over the Rosenthal et al. '864 Application in view of the abstract of Japanese Patent Publication No. 05-163424 to Suzuki et al.

For the reasons stated above, Applicant believes that the present Application is now in condition for allowance and respectfully urges the allowance of the claims presented with the entry of this Amendment. If the Examiner believes that there are additional issues to be addressed that may be resolved through a telephone interview, he is respectfully requested to contact Applicant's attorney at the telephone number provided below.

This Amendment is accompanied by a Petition extending the time for response to and including September 23, 2004. It is believed that a fee of $950.00 is due with the Petition. The Examiner is hereby authorized to charge the extension fee to Deposit Account No. 501402. If any additional fees are due, including extension and petition fees, the Examiner is hereby authorized to charge such fees to Deposit Account No. 501402.

Respectfully Submitted,

By: William Smith
Reg. No. 46,459

McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Telephone: (973) 622-4444, Ext. 4368

NWK2: 1227873.01